K132571

510(k) Summary for Elecsys CK-MB STAT and Elecsys CK-MB Immunoassays

Date prepared: October 17, 2013

Purpose of submission

Roche Diagnostics hereby submits this 510(k) to provide FDA with notification of intent to market a new device named Elecsys CK-MB Gen.4 reagent. All data in this submission was generated using the CK-MB STAT assay on the **cobas e** 411 analyzer as indicated. Method comparison data is included for the CK-MB STAT and CK-MB (18-minute) assay, as well as CK-MB STAT and Predicate device.

This candidate device is a new reagent that was developed by Roche Diagnostics. The previous generation of reagent, CK-MB STAT, was cleared in 510(k) K022654 and serves as the predicate device. The candidate and predicate devices use the same calibrator and controls. Only the reagents differ. This submission presents data to support clearance of this new reagent.

Measurand CK-MB

Type of test Quantitative colorimetric method; Cpk or Isoenzymes

Applicant

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OCT 18 2013

Candidate device names

Proprietary name:
(1) Elecsys CK-MB STAT Immunoassay
(2) Elecsys CK-MB Immunoassay

Common name:
(1) CK-MB STAT Immunoassay
(2) CK-MB Immunoassay

510(k) Summary for Elecsys CK-MB STAT and Elecsys CK-MB Immunoassays, *Continued*

Regulatory information

Product Code	Classification	Regulation	Panel
JHY	Class II	21 CFR 862.1215 (Creatine phosphokinase/creatine kinase or isoenzymes test system)	Clinical Chemistry

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510(k) Summary for Elecsys CK-MB STAT and Elecsys CK-MB Immunoassays, *Continued*

Intended use	CK-MB STAT Reagent and CK-MB Reagent have the same intended uses: Immunoassay for the *in vitro* quantitative determination of the MB isoenzyme of creatine kinase in human serum and plasma. Measurements of the MB isoenzyme of creatinine kinase are used as an aid in the diagnosis of myocardial infarction. The **electrochemiluminescence immunoassay** "ECLIA" is intended for use on the indicated Elecsys and **cobas e** immunoassay analyzers.
Indications for use	Immunoassay for the *in vitro* quantitative determination of the MB isoenzyme of creatine kinase in human serum and plasma. Measurements of the MB isoenzyme of creatinine kinase are used as an aid in the diagnosis of myocardial infarction. The **electrochemiluminescence immunoassay** "ECLIA" is intended for use on the indicated Elecsys and **cobas e** immunoassay analyzers.
Special conditions for use	For prescription use only
Special instrument requirements	The **electrochemiluminescence immunoassay** "ECLIA" is intended for use on the indicated Elecsys and **cobas e** immunoassay analyzers.
Candidate device description	The CK-MB STAT Assay and the CK-MB Assay are two-step sandwich immunoassays with streptavidin microparticles and electrochemiluminescence detection. Results are determined using a calibration curve that is generated specifically on each instrument by a 2-point calibration and a master curve (5-point-calibration) provided with the reagent bar code. The CK-MB STAT application is identical to the CK-MB assay, with the only difference being the length of incubation (9 minutes vs. 18 minutes).

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510(k) Summary for Elecsys CK-MB STAT and Elecsys CK-MB Immunoassays, *Continued*

Predicate device	Roche Diagnostics claims substantial equivalence to CK-MB, 3rd generation, immunoassay, cleared in K022654.

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510(k) Summary for Elecsys CK-MB STAT and Elecsys CK-MB Immunoassays, *Continued*

Substantial equivalence - similarities

There are two tables in this summary:

The first table compares the CK-MB STAT generation 4 immunoassay (Master Assay) with the predicate device.

The second table exhibits the comparison between CK-MB STAT generation 4 immunoassay to the CK-MB 18-minute generation 4 immunoassay.

Continued on next page

510(k) Summary for Elecsys CK-MB STAT and CK-MB, *continued*

Comparison of Assays, Similarities and Differences

Table 1 CK-MB STAT 3rd Generation vs. CK-MB STAT 4th Generation

Assay Comparison		
Feature	**Predicate Device: Elecsys 3rd Generation CK-MB STAT Assay (K022654)**	**4th Generation CK-MB STAT Assay (modified)**
General Assay Features		
Intended Use/ Indications for Use	Immunoassay for the *in vitro* quantitative determination of MB isoenzyme of creatine kinase in human serum and plasma. Measurements of the MB isoenzyme of creatine kinase are used as an aid in the diagnosis of myocardial infarction.	Same
Assay Protocol	Two-step Sandwich assay using biotinylated and ruthenium labeled antibodies and streptavidin microparticles	Same
Detection Protocol	Electrochemiluminescent Immunoassay	Same
Applications	STAT application (noted as CK-MB STAT in the labeling) and 18-minute application (noted as CK-MB in the labeling).	STAT application (noted as CK-MB STAT in the labeling)

Continued on next page

510(k) Summary for Elecsys CK-MB STAT and CK-MB, *continued*

Comparison of Assays—Similarities and Differences, *continued*

Table 1 CK-MB STAT 3rd Generation vs. CK-MB STAT 4th Generation, *continued*

Assay Comparison		
Feature	**Predicate Device: Elecsys 3rd Generation CK-MB STAT Assay (K022654)**	**4th Generation CK-MB STAT Assay (modified)**
General Assay Features		
Instrument Platform	Roche Elecsys 2010	Roche **cobas e** 411
Sample Volume	15 µL	Same
Sample Type	Human serum and plasma treated with K_3-EDTA, lithium heparin, sodium heparin and Na-citrate plasma.	Human serum and plasma treated with K_2-EDTA, K_3-EDTA, lithium heparin and sodium heparin plasma.
Reagents	Sandwich principle. Total duration of assay: 9 minutes. • 1st incubation: 15 µL of sample, a biotinylated monoclonal anti-CK-MB antibody, and a monoclonal CK-MB-specific antibody labeled with a ruthenium complex react to form a sandwich complex. • 2nd incubation: After addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin.	Same
Calibrator	CK-MB STAT CalSet (CK-MB Calset for 18-minute assay)	Same

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510(k) Summary for Elecsys CK-MB STAT and CK-MB, *continued*

Comparison of Assays—Similarities and Differences, *continued*

Table 1 CK-MB STAT 3rd Generation vs. CK-MB STAT 4th Generation, *continued*

Assay Comparison		
Feature	**Predicate Device: Elecsys 3rd Generation CK-MB STAT Assay (K022654)**	**4th Generation CK-MB STAT Assay (modified)**
General Assay Features		
Calibration Interval	Calibration must be performed once per reagent lot using fresh reagent (i.e. not more than 24 hours since the reagent kit was registered on the analyzer). Renewed calibration is recommended as follows: Elecsys 2010 analyzers: • After 1 month (28 days) when using the same reagent lot. • After 7 days (when using the same reagent kit on the analyzer). • As required: e.g. quality control findings outside the specified limits	Calibration must be performed once per reagent lot using fresh reagent (i.e. not more than 24 hours since the reagent kit was registered on the analyzer). Renewed calibration is recommended as follows: **cobas e 411** analyzers: • After 1 month (28 days) when using the same reagent lot. • After 7 days (when using the same reagent kit on the analyzer). As required: e.g. quality control findings outside the specified limits
Controls	Elecsys PreciControl Cardiac II	Same

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510(k) Summary for Elecsys CK-MB STAT and CK-MB, *continued*

Comparison of Assays—Similarities and Differences, *continued*

Table 1 CK-MB STAT 3rd Generation vs. CK-MB STAT 4th Generation, *continued*

Assay Comparison		
Feature	**Predicate Device: Elecsys 3rd Generation CK-MB STAT Assay (K022654)**	**4th Generation CK-MB STAT Assay (modified)**
General assay features		
Traceability / Standardization	The linearity of the CK-MB STAT assay was improved by using human recombinant CK-MB from Seradyn. The test was standardized against the previous Elecsys CK-MB STAT assay in the range of 0-20.0 ng/mL; this leads to up to a 30% reduction of the test results in the range of 20-500 ng/mL.	The CK-MB STAT assay is traceable to the Abbott IMx CK-MB assay and linearized using human recombinant CK-MB from Seradyn.
Reagent Stability	Unopened: 2-8°C - Up to the stated expiration date Opened 2-8°C - 12 weeks On Analyzers – 8 weeks	Unopened: 2-8°C - Up to the stated expiration date Opened 2-8°C - 12 weeks On Analyzers – 6 weeks

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510(k) Summary for Elecsys CK-MB STAT and CK-MB, *continued*

Comparison of Assays—Similarities and Differences, *continued*

Table 1 CK-MB STAT 3rd Generation vs. CK-MB STAT 4th Generation, *continued*

Assay Comparison		
Feature	**Predicate Device: Elecsys 3rd Generation CK-MB STAT Assay (K022654)**	**4th Generation CK-MB STAT Assay (modified)**
Labeled Performance Characteristics		
Measuring Range	0.1-500 ng/mL	1-300 ng/mL
Precision	*Elecsys 2010:* Within-run (will be labeled Repeatability) 1.5% CV @ 5.77 ng/mL 2.1% CV @ 12.4 ng/mL 1.8% CV @ 39.7 ng/mL 1.9% CV^{PC1} @ 5.86 ng/mL 1.9% CV^{PC2} @ 53.1 ng/mL Total (will be labeled Intermediate) 2.3% CV @ 5.77 ng/mL 2.6% CV @ 12.4 ng/mL 2.3% CV @ 39.7 ng/mL 2.4% CV^{PC1} @ 5.86 ng/mL 2.7% CV^{PC2} @ 53.1 ng/mL	*cobas e 411:* Within-run (will be labeled Repeatability) 1.2% CV @ 5.46 ng/mL 1.3% CV @ 29.5 ng/mL 1.3% CV @ 93.5 ng/mL 1.5% CV @ 301 ng/mL 0.06 SD^{PC1} @ 4.44 ng/mL 1.4% CV^{PC2} @ 57.9 ng/mL Total (will be labeled Intermediate) 2.5% CV @ 5.46 ng/mL 4.2% CV @ 29.5 ng/mL 4.1% CV @ 93.5 ng/mL 3.3% CV @ 301 ng/mL 0.12 SD^{PC1} @ 4.44 ng/mL 3.0% CV^{PC2} @ 57.9 ng/mL Precision testing was completed over 21 days, according to CLSI EP5-A2, utilizing human serum samples and PreciControl Cardiac II.
Analytical Sensitivity	Lower Detection Limit : <0.100 ng/ml	Limit of Blank (LoB): = 0.1 ng/ml Limit of Detection (LoD): = 0.3 ng/ml Limit of Quantitation (LoQ): = 1 ng/ml [1] Established according to CLSI EP17- A

PC1=PreciControl Cardiac 1
PC2=PreciControl Cardiac 2

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510(k) Summary for Elecsys CK-MB STAT and CK-MB, *continued*

Comparison of Assays—Similarities and Differences, *continued*

Table 1 CK-MB STAT 3rd Generation vs. CK-MB STAT 4th Generation, *continued*

Assay Comparison		
Feature	**Predicate Device: Elecsys 3rd Generation CK-MB STAT Assay (K022654)**	**4th Generation CK-MB STAT Assay (modified)**
Labeled Performance Characteristics		
Analytical Specificity	**Analyte** / **Reactivity** CK-MM / None CK-BB / 0.10%	Same
Hook Effect	There is no high-dose hook effect at CK-MB concentrations up to 5000 ng/mL	Same
Limitations	The assay is unaffected by: • Hemoglobin <1.5 g/dL. • Bilirubin < 34 mg/dL • Intralipid < 1,500 mg/dL • Biotin < 100 ng/mL • Rheumatoid factors ≤ 1,500 IU/mL • In vitro tests were performed on 50 commonly used pharmaceuticals. No interference with the assay was found. • In rare cases, interference due to extremely high titers of antibodies to analyte-specific antibodies, streptavidin or ruthenium can occur. These effects are minimized by suitable test design. • For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.	The assay is unaffected by: • Hemoglobin ≤1000 mg/dL. • Bilirubin ≤ 34 mg/dL • Intralipid ≤ 1,500 mg/dL • Biotin ≤ 30 ng/mL • Rheumatoid factors ≤ 1,500 IU/mL • IgG ≤ 7 g/dl • IgM ≤ 1 g/dl • IgA ≤ 1.6 g/dl • Serum Albumin ≤ 20 g/dl • In vitro tests were performed on 51 commonly used pharmaceuticals. No interference with the assay was found. • In rare cases, interference due to extremely high titers of antibodies to analyte-specific antibodies, streptavidin or ruthenium can occur. These effects are minimized by suitable test design. For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings. These limitations were established by testing performed with one human serum sample containing low levels of CK-MB and one human serum sample containing high levels of CK-MB.

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510(k) Summary for Elecsys CK-MB STAT and CK-MB, *continued*

Comparison of Assays—Similarities and Differences, continued

Table 1 CK-MB STAT 3rd Generation vs. CK-MB STAT 4th Generation, *continued*

<table>
<tr><th colspan="3">Immunoassay Comparison</th></tr>
<tr><th>Feature</th><th>Predicate Device: Elecsys 3rd Generation CK-MB STAT Assay (K022654)</th><th>4th Generation CK-MB STAT Assay (modified)</th></tr>
<tr><th colspan="3">Labeled Performance Characteristics</th></tr>
<tr><td>Method Comparison performed on Serum Samples</td><td colspan="2">
<table>
<tr><td>n = 165
Min = 1.08 ng/ml
Max = 283 ng/ml</td><td>Passing/Bablok</td><td>Linear Regression</td></tr>
<tr><td>Slope</td><td>1.053</td><td>1.067</td></tr>
<tr><td>Intercept</td><td>-0.525</td><td>-0.740</td></tr>
<tr><td>Tau/r</td><td>0.982</td><td>0.999</td></tr>
</table>
</td></tr>
<tr><td>Clinical Study/ Reference Range Study</td><td colspan="2">
<table>
<tr><td></td><td>N</td><td>Median</td><td>97.5th percentile (ng/mL)</td><td>99th percentile (ng/mL)</td></tr>
<tr><td>Women</td><td>760</td><td>0.97</td><td>2.88</td><td>3.77</td></tr>
<tr><td>Men</td><td>628</td><td>1.35</td><td>4.94</td><td>6.73</td></tr>
</table>
<table>
<tr><td></td><td>Gender</td><td>(N)</td><td>99th percentile (ng/mL)</td></tr>
<tr><td>All Subjects</td><td>Female</td><td>523</td><td>5.34</td></tr>
<tr><td></td><td>Male</td><td>568</td><td>10.36</td></tr>
<tr><td>Subjects with no Self-reported risk factors</td><td>Female</td><td>120</td><td>4.30</td></tr>
<tr><td></td><td>Male</td><td>102</td><td>7.70</td></tr>
</table>
Subjects represented "apparently heart healthy" population with exclusion of subjects with known poor cardiac health or known peripheral vascular disease only.
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</table>

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510(k) Summary for Elecsys CK-MB STAT and CK-MB, *continued*

Comparison of Assays—Similarities and Differences, continued

Matrix Comparison

Sodium-heparin, lithium-heparin, K2-EDTA, and K3-EDTA are permissible anticoagulants for use with this reagent because they do not interfere with recovery of CK-MB. In an internal study, 35 tubes were collected per anticoagulant. Plasma results were compared to serum results and percent recovery was determined. In terms of percent recovery, all data passed the following criteria:

- Slope: 0.9-1.1
- Coefficient of correlation: Pearson r > 0.95
- Intercept: $\leq \pm 0.15$
- For single sample pairs: 100% ±20% based on reference

Anticoagulant	Sample Concentration Range Tested (ng/mL)	Claimed Measuring Range (ng/mL)
Na-heparin	1.46-297.83	1.00 – 300 ng/mL
Li-heparin	1.39-244.83	
K_2-EDTA	1.58-299.65	
K_3-EDTA	1.56-291.89	

In addition, method comparisons with plasma vs. serum were calculated with the following results:

Serum vs. Na-heparin Plasma : P/B: y = 0.994x + (-0.0100), r = 0.9997

Serum vs. Li-heparin Plasma: P/B: y = 0.9960x + (0.0045), r = 0.9996

Serum vs. K_2-EDTA Plasma: P/B: y = 1.020x + (-0.0082), r = 0.9999

Serum vs. K_3-EDTA Plasma: P/B: y = 0.988x + (-0.0115), r = 0.9998

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510(k) Summary for Elecsys CK-MB STAT and CK-MB, *continued*

Table 2 4th Generation STAT vs. 4th Generation 18-Minute

Assay Comparison		
Feature	**4th Generation CK-MB STAT Assay**	**4th Generation CK-MB 18-Minute assay (modified)**
General Assay Features		
Intended Use/ Indications for Use	Immunoassay for the *in vitro* quantitative determination of MB isoenzyme of creatine kinase in human serum and plasma. Measurements of the MB isoenzyme of creatine kinase are used as an aid in the diagnosis of myocardial infarction.	Same
Assay Protocol	Two step Sandwich assay using biotinylated and ruthenium labeled antibodies and streptavidin microparticles	Same
Detection Protocol	Electrochemiluminescent Immunoassay	Same
Applications	STAT application (noted as CK-MB STAT in the labeling)	18-minute application (noted as CK-MB in the labeling).

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510(k) Summary for Elecsys CK-MB STAT and CK-MB, *continued*

Comparison of Assays—Similarities and Differences, *continued*

Table 2 4th Generation STAT vs. 4th Generation 18-Minute, *continued*

Assay Comparison		
Feature	**4th Generation CK-MB STAT Assay**	**4th Generation CK-MB 18-minute assay (modified)**
General Assay Features		
Instrument Platform	Roche **cobas c** 411	Same
Sample Volume	15 µL	Same
Sample Type	Human serum and plasma treated with K_2-EDTA, K_3-EDTA, lithium heparin and sodium heparin plasma.	Same.
Reagents	Sandwich principle. Total duration of assay: 9 minutes. • 1st incubation: 15 µL of sample, a biotinylated monoclonal anti-CK-MB antibody, and a monoclonal CK-MB-specific antibody labeled with a ruthenium complex react to form a sandwich complex. • 2nd incubation: After addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin	Sandwich principle. Total duration of assay: 18 minutes. • 1st incubation: 15 µL of sample, a biotinylated monoclonal anti-CK-MB antibody, and a monoclonal CK-MB-specific antibody labeled with a ruthenium complex react to form a sandwich complex. • 2nd incubation: After addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin
Calibrator	CK-MB STAT CalSet	CK-MB CalSet

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510(k) Summary for Elecsys CK-MB STAT and CK-MB, *continued*

Comparison of Assays—Similarities and Differences, *continued*

Table 2 4th Generation STAT vs. 4th Generation 18-Minute, *continued*

Assay Comparison		
Feature	**4th Generation CK-MB STAT Assay**	**4th Generation CK-MB 18-minute assay (modified)**
General Assay Features		
Calibration Interval	Calibration must be performed once per reagent lot using fresh reagent (i.e. not more than 24 hours since the reagent kit was registered on the analyzer). Renewed calibration is recommended as follows: **cobas e 411** analyzers: • After 1 month (28 days) when using the same reagent lot. • After 7 days (when using the same reagent kit on the analyzer). • As required: e.g. quality control findings outside the specified limits	Same
Controls	Elecsys PreciControl Cardiac II	Same

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510(k) Summary for Elecsys CK-MB STAT and CK-MB, *continued*

Comparison of Assays—Similarities and Differences, *continued*

Table 2 4th Generation STAT vs. 4th Generation 18-Minute, *continued*

Assay Comparison		
Feature	**4th Generation CK-MB STAT Assay**	**4th Generation CK-MB 18-Minute Assay (modified)**
General assay features		
Traceability / Standardization	The CK-MB STAT assay is traceable to the Abbott IMx CK-MB assay and linearized using human recombinant CK-MB from Seradyn.	Same
Reagent Stability	Unopened: 2-8°C - Up to the stated expiration date Opened 2-8°C - 12 weeks On Analyzers – 6 weeks	Same

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510(k) Summary for Elecsys CK-MB STAT and CK-MB, *continued*

Comparison of Assays—Similarities and Differences, continued

Table 2 4th Generation STAT vs. 4th Generation 18-Minute, *continued*

Assay Comparison		
Feature	**4th Generation CK-MB STAT Assay**	**4th Generation CK-MB 18-minute assay (modified)**
Labeled Performance Characteristics		
Measuring Range	1-300 ng/mL	same
Precision according to CLSI EP5-A2	*cobas e 411:* Within-run (will be labeled Repeatability) 1.2% CV @ 5.46 ng/mL 1.3% CV @ 29.5 ng/mL 1.3% CV @ 93.5 ng/mL 1.5% CV @ 301 ng/mL 0.06 SD^{PC1} @ 4.44 ng/mL 1.4% CV^{PC2} @ 57.9 ng/mL Total (will be labeled Intermediate) 2.5% CV @ 5.46 ng/mL 4.2% CV @ 29.5 ng/mL 4.1% CV @ 93.5 ng/mL 3.3% CV @ 301 ng/mL 0.12 SD^{PC1} @ 4.44 ng/mL 3.0% CV^{PC2} @ 57.9 ng/mL Precision testing was completed over 21 days, according to CLSI EP5-A2, utilizing human serum samples and PreciControl Cardiac II.	*cobas e 411:* Within-run (will be labeled Repeatability) 1.3% CV @ 5.27 ng/mL 1.4% CV @ 28.4 ng/mL 1.2% CV @ 91.2 ng/mL 1.3% CV @ 297 ng/mL 0.06 SD^{PC1} @ 4.25 ng/mL 1.2% CV^{PC2} @ 54.7 ng/mL Total (will be labeled Intermediate) 2.0% CV @ 5.27 ng/mL 2.4% CV @ 28.4 ng/mL 2.6% CV @ 91.2 ng/mL 2.0% CV @ 297 ng/mL 0.10 SD^{PC1} @ 4.25 ng/mL 2.3% CV^{PC2} @ 54.7 ng/mL Precision testing was completed over 21 days, according to CLSI EP5-A2, utilizing human serum samples and PreciControl Cardiac II.
Analytical Sensitivity[1] according to CLSI EP17-A	Limit of Blank (LoB): = 0.1 ng/ml Limit of Detection (LoD): = 0.3 ng/ml Limit of Quantitation (LoQ): = 1 ng/ml	Same

PC1=PreciControl Cardiac 1
PC2=PreciControl Cardiac 2

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510(k) Summary for Elecsys CK-MB STAT and CK-MB, *continued*

Comparison of Assays—Similarities and Differences, *continued*

Table 2 4th Generation STAT vs. 4th Generation 18-Minute, *continued*

Assay Comparison		
Feature	**4th Generation CK-MB STAT Assay**	**4th Generation CK-MB 18-minute assay (modified)**
Labeled Performance Characteristics		
Analytical Specificity	**Analyte** / **Reactivity** CK-MM / none CK-BB / 0.10%	Same
Hook Effect	There is no high-dose hook effect at CK-MB concentrations up to 5000 ng/mL	Same
Limitations	The assay is unaffected by: • Hemoglobin ≤1000 mg/dL. • Bilirubin ≤ 34 mg/dL • Intralipid ≤ 1,500 mg/dL • Biotin ≤ 30 ng/mL • Rheumatoid factors ≤ 1,500 IU/mL • IgG ≤ 7 g/dl • IgM ≤ 1 g/dl • IgA ≤ 1.6 g/dl • Serum Albumin ≤ 20 g/dl • In vitro tests were performed on 51 commonly used pharmaceuticals. No interference with the assay was found. • In rare cases, interference due to extremely high titers of antibodies to analyte-specific antibodies, streptavidin or ruthenium can occur. These effects are minimized by suitable test design. For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings. These limitations were established by testing performed with one human serum sample containing low levels of CK-MB and one human serum sample containing high levels of CK-MB.	Same.

Continued on next page

510(k) Summary for Elecsys CK-MB STAT and CK-MB, *continued*

Comparison of Assays—Similarities and Differences, *continued*

Table 2 4th Generation STAT vs. 4th Generation 18-Minute, *continued*

<table>
<tr><th colspan="3">Immunoassay Comparison</th></tr>
<tr><th>Feature</th><th>4th Generation CK-MB STAT Assay</th><th>4th Generation CK-MB 18-minute assay (modified)</th></tr>
<tr><th colspan="3">Labeled Performance Characteristics</th></tr>
<tr><td>Method Comparison completed using Serum Samples</td><td colspan="2"><table>
<tr><td>n = 115
Min = 1.44 ng/ml
Max = 283 ng/ml</td><td>Passing/Bablok</td><td>Linear Regression</td></tr>
<tr><td>Slope</td><td>1.003</td><td>1.006</td></tr>
<tr><td>Intercept</td><td>-0.005</td><td>0.071</td></tr>
<tr><td>Tau/r</td><td>0.985</td><td>0.999</td></tr>
</table></td></tr>
</table>

[1] Description of Analytical Sensitivity according to CLSI EP17-A

The Limit of Blank, Limit of Detection and Limit of Quantitation were determined in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP17-A requirements.

The Limit of Blank is the 95th percentile value from $n \geq 60$ measurements of analyte-free samples over several independent series. The Limit of Blank corresponds to the concentration below which analyte-free samples are found with a probability of 95 %.

The Limit of Detection is determined based on the Limit of Blank and the standard deviation of low concentration samples. The Limit of Detection corresponds to the lowest analyte concentration which can be detected (value above the Limit of Blank with a probability of 95 %).

The Limit of Quantitation is defined as the lowest amount of analyte in a sample that can be accurately quantitated with a total allowable error of ≤ 20 %.

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510(k) Summary Elecsys CK-MB STAT and CK-MB, *continued*

Standard/ Guidance Document Reference

In addition to FDA guidance regarding 510(k) submissions, the following standards were used for the performance studies.

- Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition. CLSI document EP5-A2, Volume 24, No. 25, August 2004.

- Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline. CLSI document EP 17-A, Volume 24, No. 34, October 2004.

- Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline. CLSI document EP6-A, Volume 23, No. 16, April 2003.

Conclusion

The submitted information in this premarket notification supports a substantial equivalence decision.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 18, 2013

Roche Diagnostics
C/O Kelli Turner
9115 Hague Road
INDIANAPOLIS IN 46250-0416

Re: k132571
Trade/Device Name: Elecsys CK-MB STAT Immunoassay, Elecsys CK-MB Immunoassay
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: II
Product Code: JHY
Dated: August 14, 2013
Received: August 15, 2013

Dear Ms. Turner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for

the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K132571

Device Name: Elecsys CK-MB STAT Immunoassay

Indications for Use:

Immunoassay for the *in vitro* quantitative determination of the MB isoenzyme of creatine kinase in human serum and plasma. Measurements of the MB isoenzyme of creatinine kinase are used as an aid in the diagnosis of myocardial infarction.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and **cobas e** immunoassay analyzers.

Prescription Use ___X____ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Ruth A. Chesler -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k132571

Indications for Use Form

510(k) Number (if known): K132571

Device Name: Elecsys CK-MB Immunoassay

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(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Ruth A. Chesler -S

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